EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	C. A. No. 22-252-MSG **JURY TRIAL DEMANDED** **HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL'S EYES ONLY - FILED UNDER SEAL**

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") file this Complaint seeking patent infringement damages against Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") and allege the following:

INTRODUCTION

1. The impact of the COVID-19 pandemic, one of the greatest public health challenges in modern history, would be immeasurably worse but for the rapid, widespread availability of cutting-edge mRNA-based vaccines like Moderna's. Moderna brought its vaccine from lab bench to arms in record speed. That unprecedented accomplishment was made possible by Moderna's use of breakthrough technology Arbutus had already created and patented—a revolutionary lipid nanoparticle ("LNP") delivery platform that took the scientists of Arbutus years of painstaking work to develop and refine. Moderna was well aware of Arbutus's LNP patents and licensed them for other product programs, but it chose not to do so for its COVID-19 vaccine. Instead, it attempted to invalidate several of the patents before the United States Patent and Trademark Office, and when those efforts largely failed, Moderna simply used the patented

technology without paying for it or even asking for a license. Plaintiffs do not seek an injunction or any relief in this case that would impede the sale or manufacture of Moderna's life-saving vaccine. They seek only fair compensation for the use of patented technology they developed with great effort and at great expense, without which Moderna's COVID-19 vaccine would not have been successful.

2. Medicines using messenger ribonucleic acid (or "mRNA") technology, like Moderna's COVID-19 vaccine, rely on synthetic mRNA that enters the body's cells and instructs them to make proteins they would not necessarily make on their own. Moderna's COVID-19 vaccine, in particular, uses mRNA to cause cells to make a small piece of the virus that causes COVID-19 called the "spike protein." That small piece, which is harmless in isolation, prompts the body's immune system to produce antibodies that will recognize the spike protein if it is encountered in the future and destroy it. In this way, the vaccine equips a person's body ahead of time with antibodies to fight the COVID-19 virus if that person experiences a subsequent exposure.

3. Ever since the vast potential for mRNA-based vaccines and other mRNA-based medicines began to catch the attention of scientists more than two decades ago, the biggest technological hurdle to developing and deploying them has been devising a safe and effective way to deliver the mRNA to the cell. Without adequate protection, mRNA quickly degrades in the body. For mRNA vaccines like Moderna's to work, they must incorporate a mechanism for protecting the fragile mRNA, delivering it through cell membranes, and then releasing it inside

the cell. In the words of one Nobel Prize winning scientist, the secret for making RNA-based products work has always been "delivery, delivery, delivery."[1]

4. Having vexed experts in the field for years, that problem eventually found a solution in the innovative research of Arbutus scientists. Their solution was ingenious: microscopic particles built from four carefully selected types of fat-like molecules, so small that they are measured in nanometers but still stable enough to shelter and protect an RNA molecule on a voyage through the human body to a target cell, and then through the target cell's membrane, before finally releasing the RNA. These tiny fat-like particles are called "lipid nanoparticles," or "LNPs." The United States Patent and Trademark Office has granted Arbutus several patents for its groundbreaking LNP technologies.

5. LNPs identified through Arbutus's pioneering work have been described as "crucial" to Moderna's COVID-19 vaccine, the first mRNA product the company was able to commercialize and the keystone of its financial success.[2] Without the LNPs Arbutus invented to safeguard the mRNA and deliver it into cells, the mRNA in Moderna's vaccine would degrade before ever reaching the cells it needs to enter and the vaccine would not work.

6. Moderna has long been aware of Arbutus's LNP intellectual property and its importance as a component of mRNA-based vaccines and other mRNA-based medicines. Several years before the pandemic, Moderna obtained licenses to use Arbutus's LNP patents for certain mRNA products directed to specific viral targets. But those licenses did not grant Moderna rights to use the technology for products targeting SARS-CoV-2, the virus that causes

[1] Erika Check, "RNA to the Rescue," *Nature* 425:10-12 (2003), *available at* https://www.nature.com/articles/425010a.
[2] Nathan Vardi, "Moderna's Mysterious Coronavirus Vaccine Delivery System," *Forbes.com*, July 29, 2020, *available at* https://www.forbes.com/sites/nathanvardi/2020/07/29/modernas-mysterious-coronavirus-vaccine-delivery-system/.

COVID-19 and that the vaccines at issue here target. Before it decided to use Arbutus's proven and patented technology as a crucial part of its COVID-19 vaccine, Moderna did not ask for a license to do so. Instead, it tried to convince the United States Patent and Trademark Office and, later, the United States Court of Appeals for the Federal Circuit to cancel several of Arbutus's LNP-related patents. But despite the failure of Moderna's attempts to eliminate Arbutus's patents, and despite Plaintiffs' efforts to resolve this dispute without litigation, Moderna has remained unwilling to pay for its use of Arbutus's technology in a vaccine that has earned Moderna billions of dollars in profits.

7. Moderna's intransigence has forced Arbutus and Genevant, a company spearheaded by former Arbutus scientists, to bring this infringement action. Plaintiffs are proud that their LNP technology has had such a profound impact on the heroic fight against the COVID-19 pandemic, and they do not seek to impede by an injunction or otherwise the production or distribution of Moderna's COVID-19 vaccine, including boosters. All Plaintiffs seek is the compensation due to them under the patent laws of the United States and as a matter of simple fairness.

NATURE OF THE ACTION

8. This is a civil action under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, seeking damages for Moderna's infringing manufacture, use, sale, offer for sale, and/or importation of, and/or the supplying from the United States of a component or all or a substantial portion of the components of, its mRNA-1273 COVID-19 mRNA LNP vaccine product ("Moderna's COVID-19 vaccine") or any supplemental or booster COVID-19 mRNA LNP vaccine product (collectively, the "Accused Product").

9. As alleged herein, the manufacture, use, sale, offer to sell, and/or importation of the Accused Product, and/or the supplying from the United States of a component or all or a substantial portion of the components of the Accused Product infringes or will infringe, actively induces or will actively induce infringement of, or contributes or will contribute to the infringement of, one or more claims of the following patents relating to nucleic acid-lipid particles, compositions thereof, and their use to deliver nucleic acid-based medicines: U.S. Patent Nos. 8,058,069 (Exhibit A), 8,492,359 (Exhibit B), 8,822,668 (Exhibit C), 9,364,435 (Exhibit D), 9,504,651 (Exhibit E), and 11,141,378 (Exhibit F) (collectively, the "Asserted Patents"). At all relevant times, Arbutus owned the Asserted Patents and licensed exclusive rights to sublicense, practice, and sue for infringement of them to Genevant in certain fields of use that include the vaccine application at issue in this Complaint, with certain exceptions not relevant here (hereinafter, Genevant's "Exclusive Rights").

THE PARTIES

10. Plaintiff Arbutus Biopharma Corporation is a corporation organized and existing under the laws of Canada, with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania, 18974. The company's research and development efforts include discovering, developing, and commercializing a cure for chronic hepatitis B virus, as well as drug discovery and development efforts for treating coronaviruses, including SARS-CoV-2, which causes COVID-19.

11. Plaintiff Genevant Sciences GmbH is a company organized and existing under the laws of Switzerland, with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland. Genevant is a technology-focused nucleic acid delivery solutions company with cutting-edge LNP platforms. Genevant owns or licenses the industry's most important LNP

intellectual property—that of Arbutus—and has decades of experience and expertise in nucleic acid drug delivery and development. Genevant, together with its affiliated companies, maintains offices in Cambridge, Massachusetts and Vancouver, British Columbia, Canada. Genevant's mission is to utilize its LNP and other technologies to deliver innovative new medicines that use mRNA or other nucleic acids.

12. Defendant Moderna, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139. Moderna, Inc., itself and through its subsidiary ModernaTX, Inc., develops, manufactures, imports, markets, distributes, offers to sell, and/or sells vaccines and other medicines in the State of Delaware and throughout the United States, for use in the State of Delaware and throughout the United States.

13. Defendant ModernaTX, Inc. is a wholly owned subsidiary of Moderna, Inc. (collectively, "Moderna"). ModernaTX, Inc. is also a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139. ModernaTX, Inc. develops, manufactures, imports, markets, distributes, offers to sell, and/or sells vaccines and other medicines in the State of Delaware and throughout the United States, for use in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

A. Subject-Matter Jurisdiction

14. Because this is an action for infringement under the patent laws of the United States, Title 35 of the United States Code, the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

B. Personal Jurisdiction

15. This Court has personal jurisdiction over Moderna because, among other things, Moderna, Inc. and ModernaTX, Inc. have purposefully availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. Because Defendants are organized and exist under the laws of Delaware, are qualified to do business in Delaware, and have appointed registered agents for service of process in Delaware, Moderna, Inc. and ModernaTX, Inc. have consented to general jurisdiction in Delaware.

16. Additionally, Moderna, Inc. and ModernaTX, Inc., directly or through others, make, use, induce others to use, offer for sale, and/or sell the Accused Product, and/or a component, combination, or composition constituting a material part of the Accused Product, within the United States, and/or import the same into the United States, including into the District of Delaware. For example, on December 18, 2020, Moderna received Emergency Use Authorization ("EUA") from the United States Food and Drug Administration ("FDA") for its COVID-19 vaccine to be distributed and administered to people throughout the United States, including in the District of Delaware and, on January 31, 2022, the FDA approved Moderna's Biologics License Application ("BLA") for its COVID-19 vaccine. Upon information and belief, as of February 24, 2022, over 835,000 doses of Moderna's COVID-19 vaccine have been delivered to the State of Delaware.[3] Therefore, Moderna, Inc. and ModernaTX, Inc. transact business within Delaware relating to Plaintiffs' claims and have engaged in systematic and continuous business contacts here.

[3] Delaware Environmental Public Health Tracking Network, Vaccine Tracker, https://myhealthycommunity.dhss.delaware.gov/locations/state/vaccine-tracker (last visited Feb. 25, 2022).

17. For the above reasons, there is nothing unreasonable or fundamentally unfair about requiring Moderna, Inc. and ModernaTX, Inc. to litigate this action in this District, and the Court has personal jurisdiction over them here.

C. Venue

18. Venue is proper in this District under 28 U.S.C. §§ 1391(c)(2) and 1400(b) because both Moderna, Inc. and ModernaTX, Inc. are corporations organized and existing under the laws of the State of Delaware and are therefore subject to suit in this District.

BACKGROUND

A. How Vaccines Work

19. Viruses are typically small packets of DNA or RNA. If a virus enters a living host cell—for example, after being ingested, transmitted through bodily fluids, or inhaled through a person's mouth or nose—the virus's DNA or RNA hijacks the cell's machinery and instructs the cell to make copies of the virus. These copies, often numbering into the millions, leave the infected cell and enter other cells where the process repeats. Infected cells can be damaged or die while hosting the virus. Left unchecked, the host organism itself can die.

20. Although vaccines targeting viruses have different mechanisms of action, they traditionally work by injecting into the body a weakened or inactive form of the virus that is unable to cause infection, but nonetheless retains features of the infectious virus and can teach the immune system to recognize and attack the infectious virus if it invades in the future.

B. Nucleic Acid Medicines and Delivery Technologies

21. Moderna's COVID-19 vaccine belongs to a new class of medicines that deliver nucleic acids into the cells of the body to treat diseases or, in the case of Moderna's COVID-19 vaccine, to trigger an immune response to protect a person from future infection.

22. Nucleic acids are molecules that encode the genetic information essential to sustain all forms of life. One type of nucleic acid is deoxyribonucleic acid, or "DNA," which is found in our chromosomes. In humans, each person (except identical twins) has a unique set of genetic information in the "genes" within his or her chromosomes. Among other things, these genes spell out the instructions for producing proteins that make our cells and bodies function.

23. In order to make the protein encoded by a particular gene, the cell first converts the genetic code in the gene's DNA into another type of nucleic acid known as messenger ribonucleic acid, or "mRNA." mRNA is effectively a copy of the portion of DNA that the cell's protein-making machinery uses as a blueprint to assemble the protein encoded by the gene.

24. Vaccines and other medicines using ribonucleic acid, or "RNA," technologies are an emerging frontier with the potential to revolutionize medicine. RNA-based medicines can employ a type of RNA called small interfering RNA ("siRNA") to treat certain diseases by interfering with the expression of unwanted proteins to reduce the amounts produced—a process called RNA interference ("RNAi"). RNA-based medicines also can employ mRNA to cause or increase the production of certain proteins. mRNA vaccines, for example, cause cells to express a protein (or a piece of a protein) that is normally found on a particular tumor or that is part of a particular virus. The presence of that protein (or piece of a protein) teaches the body's immune system to recognize it if it is encountered in the future and destroy it. These and other RNA-based medicines hold great promise for addressing many previously intractable diseases and, as in the present circumstances, new viruses that cause or threaten worldwide pandemics.

25. Despite their promise, however, RNA-based medicines have been difficult to develop. By their nature, RNA molecules are fragile. Without adequate protection, RNA molecules are susceptible to degradation in the body, and, if and when they get to a cell, cannot

cross the cell membrane to enter the cell. For decades, the need for an effective delivery technology had been the most significant challenge in the development of RNA-based products. In particular, without the means to protect mRNA and facilitate its entry into target cells, mRNA-based vaccines and other medicines have been ineffective.

26. Indeed, functional RNA-based medicines eluded researchers until the pioneering work by Arbutus scientists, many now at Genevant companies, resulting in the discovery and development of the leading nucleic acid delivery technology in use today. Decades ago, a group of ambitious research scientists working at a predecessor company to Arbutus began to tackle the nucleic acid delivery problem that had long stymied the field. Years of tireless effort by these scientists resulted in a solution to the problem. The solution was LNP technology that relies on fat-like molecules called lipids that encapsulate and protect nucleic acids like mRNA from degradation in the body and enable them to cross cell membranes. Once inside a cell, the LNP releases the nucleic acid it encapsulates so that, in the case of an mRNA vaccine for example, the nucleic acid can express the protein it encodes.

27. The lipid components of the Arbutus technology include: structural lipids, such as phospholipids and cholesterol; "cationic" (positive charge-bearing) lipids, including "ionizable" lipids that are positive charge-bearing at certain pH levels; and conjugated lipids, which are lipids attached to a polymer such as polyethyleneglycol ("PEG"). Arbutus scientists discovered that nucleic acid-lipid particles combining particular lipid components in particular ratios could achieve much more effective delivery of nucleic acids through cell membranes and into cells.

28. These Arbutus scientists spent more than a decade researching and developing this nucleic acid-lipid delivery technology. Their efforts led to the first FDA-approved RNA-based therapeutic in the form of a drug called Onpattro®, an RNAi treatment for a form of

amyloidosis, a rare disease that causes certain proteins to accumulate in organs. The company that developed Onpattro®, Alnylam Pharmaceuticals, did so under an LNP license from Arbutus and received FDA approval in August 2018. Building on this initial success, Arbutus has granted licenses to its LNP technology to other companies, and Genevant now has several ongoing LNP product development collaborations, some directed to COVID-19 and some directed to other diseases and disorders. Several entities developing mRNA-LNP vaccines against COVID-19 have come to Genevant for a license to Arbutus's technology, including companies that have produced promising candidates in clinical trials. And Genevant's COVID-19 development collaborations include efforts to provide a vaccine to parts of the developing world.

C. The United States Awards Patents Recognizing Arbutus's Innovations

29. In recognition of Arbutus's extensive and groundbreaking research and development efforts, the United States Patent and Trademark Office has granted several families of patents claiming nucleic acid-lipid particles and lipid vesicles, as well as compositions and methods of using them. The Asserted Patents are among them:

a. U.S. Patent No. 8,058,069, "Lipid Formulations for Nucleic Acid Delivery," issued on November 15, 2011 (the "'069 Patent").

b. U.S. Patent No. 8,492,359, "Lipid Formulations for Nucleic Acid Delivery," issued on July 23, 2013 (the "'359 Patent").

c. U.S. Patent No. 8,822,668, "Lipid Formulations for Nucleic Acid Delivery," issued on September 2, 2014 (the "'668 Patent").

d. U.S. Patent No. 9,364,435, "Lipid Formulations for Nucleic Acid Delivery," issued on June 14, 2016 (the "'435 Patent").

e. U.S. Patent No. 9,504,651, "Lipid Compositions for Nucleic Acid Delivery," issued on November 29, 2016 (the "'651 Patent").

f. U.S. Patent No. 11,141,378, "Lipid Formulations for Nucleic Acid Delivery," issued on October 12, 2021 (the "'378 Patent").

30. True and correct copies of the Asserted Patents are attached hereto as Exhibits A through F. All are valid and enforceable under United States patent laws. All are assigned to and owned by Arbutus, and, at all times since Arbutus and Genevant entered into a license agreement, Genevant has held Exclusive Rights to all of the Asserted Patents in various fields of use including the vaccine application at issue here. Under the terms of the license, Genevant's Exclusive Rights include the right to sue for the infringement alleged in this Complaint.

D. Moderna's Knowledge of, and Background with, the Asserted Patents

31. Moderna has been on actual notice of Arbutus's patents since before its development of the Accused Product and has knowingly used Arbutus's technology as an essential component of its nucleic acid products and product candidates, including its COVID-19 vaccine.

32. Years before the COVID-19 pandemic, Moderna recognized that Arbutus's LNP technology could fuel its own work in RNA-based vaccines and other medicines. Accordingly, in or about May 2015, Moderna attempted to acquire rights to Arbutus's LNP delivery technology for four specific viral targets (none of which is COVID-19) through sublicense from a Canadian company called Acuitas Therapeutics. Although Acuitas had licensed Arbutus's LNP technology in 2012, its license agreement expressly limited Acuitas's ability to grant sublicenses. That limitation prohibited Acuitas from granting the sublicense that it granted to Moderna.

33. In August 2016, after learning of the Moderna-Acuitas sublicense agreements, Arbutus notified Acuitas of material breach. In October 2016, Acuitas filed suit in the Supreme Court of British Columbia seeking to prevent Arbutus from terminating the Arbutus-Acuitas agreement. Arbutus counterclaimed for a declaration that the license had been terminated and sought an injunction barring Acuitas from further sublicensing Arbutus's LNP technology.

34. In February 2018, Arbutus and Acuitas settled their dispute. The settlement agreement provided that Acuitas no longer could use Arbutus's LNP technology, with the four specific sublicenses to Moderna for vaccines targeting specific viruses remaining in effect. SARS-CoV-2, the virus that causes COVID-19 and the target of the vaccine accused of infringement in this Complaint, is not among the surviving sublicenses.

35. Deprived of a broad license to Arbutus's valuable LNP technology and hoping to make unrestricted use of that technology without having to pay royalties, Moderna began filing *inter partes* review ("IPR") petitions requesting that the Patent and Trademark Office cancel certain of Arbutus's patents, including some asserted here.

36. Moderna's first IPR petition, filed in February 2018, challenged Arbutus's U.S. Patent No. 9,404,127 ("the '127 Patent"), which, like the Asserted Patents, is directed to Arbutus's LNP technology. The Patent Trial and Appeal Board ("PTAB") ruled that all claims of the '127 Patent should be cancelled. An appeal of that decision remains pending before the United States Court of Appeals for the Federal Circuit.

37. Moderna's IPRs against the Asserted Patents were less successful. Its second IPR petition, filed in March 2018, ended with the PTAB rejecting Moderna's arguments challenging the validity of ten of the '435 Patent's twenty claims. Moderna challenged that ruling on appeal,

but in a December 2021 decision, the United States Court of Appeals for the Federal Circuit dismissed Moderna's appeal for lack of standing.[4]

38. Moderna's third IPR petition, filed in January 2019, was even less successful. The PTAB completely rejected Moderna's challenge to all claims of the '069 Patent, and the United States Court of Appeals for the Federal Circuit affirmed that ruling in December 2021.

E. Moderna Designs Its COVID-19 Vaccine Over a Single Weekend Aided by the Unauthorized Use of Arbutus's LNP Technology

39. On January 10, 2020, with the novel SARS-CoV-2 virus quickly spreading around the world, scientists identified the virus's complete genetic sequence and posted it for free on the internet. This public disclosure revealed the complete RNA sequence that encodes the virus's components, including its distinctive "spike protein." With that information in the public domain, researchers around the world were able to begin designing vaccines to target the virus.

40. Moderna was one of many companies that began work on a vaccine in earnest once the genetic sequence was published.

41. Relying on Arbutus's LNP technology covered by the Asserted Patents, Moderna was able to begin producing its COVID-19 vaccine *within just a few days* of the SARS-CoV-2 genomic sequence entering the public domain. The design component of the effort was even faster: According to Moderna President Stephen Hoge, "[w]e did it in an hour, and it worked brilliantly."[5] Compared to the timelines of prior vaccine-development efforts, Moderna's

[4] Arbutus cross-appealed the PTAB's decision, challenging the invalidation of the ten claims of the '435 Patent that were not upheld. On December 1, 2021, the Federal Circuit affirmed the PTAB's decision as to those claims.

[5] "Stephen Hoge, MD '03: Turns out, designing a COVID vaccine was easy," UCSF Alumni, *available at* https://alumni.ucsf.edu/stories/stephen-hoge.

accomplishment was unprecedented. In the words of Moderna's CEO Stéphane Bancel, "11 months since the DNA sequence of the virus became available, you will have two approved mRNA vaccines, which has never happened before with any technology. That is amazing."[6]

42. Moderna's success was chronicled in an article first published online on June 11, 2020, by individuals affiliated with the company and collaborators at the National Institutes of Health. According to this article—the "Moderna/NIH preprint"—"the release of SARS-CoV-2 sequences triggered immediate rapid manufacturing of an mRNA vaccine" by Moderna.[7] Moderna "decide[d] on [the] mRNA-1273 sequence" on January 13, 2020, just three days after the publication of the viral sequence, and "initiate[d] cGMP production" the very next day, on January 14, 2020.[8] On February 24, 2020, Moderna shipped clinical drug product, and, less than a month later, Phase I trials began.[9]

43. Moderna's COVID-19 vaccine could not have been developed, much less on a timeline unprecedented in human history, without Arbutus's proven and patented LNP delivery technology—technology that had transformed vaccine design from a years-long project into one that could be performed within an hour over a January weekend.

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[6] Antonio Regalado, "'None of us were ready' to manufacture genetic vaccines for a billion people," MIT Technology Review (December 17, 2020), *available at* https://www.technologyreview.com/2020/12/17/1014989/moderna-vaccine-availability-stephane-bancel-ceo/.
[7] "SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness," bioRvix.org (June 11, 2020) *available at* https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1.full.
[8] *Id.*
[9] *Id.*

44. Moderna's co-founder Robert Langer has been quoted as saying "I don't think people realized just how important the delivery systems are . . . ."[10] LNPs are so crucial to Moderna's mRNA vaccines that Giuseppe Ciaramella, head of infectious diseases at Moderna from 2014 to 2018, called LNPs "the unsung hero of the whole thing,"[11] while Moderna CEO Stéphane Bancel stated in December 2020 that "[w]e always said it is . . . about developing the right delivery technology. And this is something that takes years, not two weeks."[12]

45. The Moderna/NIH preprint detailed Moderna's use of Arbutus's LNP technology and its infringement of the Asserted Patents. The scientists who worked on the vaccine and contributed to the article explained that Moderna's COVID-19 vaccine is composed of mRNA encoding a modified version of the SARS-CoV-2 spike (S) protein that was synthesized, purified, "and encapsulated into lipid nanoparticles (LNP)," with a lipid molar ratio of "50:10:38.5:1.5 (ionizable lipid:DSPC:cholesterol:PEG-lipid)." Specifically, the Moderna/NIH preprint indicates that the Accused Product includes lipid particles comprising the following lipids in the following ratio: 50 mol % of an ionizable lipid that is cationic; 10 mol % of a phospholipid (DSPC); 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles (PEG-lipid).

46. These components are within the ranges of, among other claims of the Asserted Patents, Claim 1 of Arbutus's '069 Patent, which recites a "nucleic acid-lipid particle comprising (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid

[10] Tim Loh, "Lipids Are Delivering the Vaccine Revolution," Bloomberg (March 6, 2021), *available at* https://www.bloomberg.com/news/newsletters/2021-03-06/lipids-are-delivering-the-vaccine-revolution.
[11] Ryan Cross, "Without these lipid shells, there would be no mRNA vaccines for COVID-19," C&EN (March 6, 2021), *available at* https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8.
[12] Regalado, *supra* note 7.

present in the particle: (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 4 mol % to 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

47. A month after the Moderna/NIH preprint appeared, the PTAB rejected Moderna's IPR challenge to the '069 Patent in its entirety, triggering a ten percent drop in Moderna's share price in a single day. Although Moderna promptly issued public statements denying any infringement, it has been conspicuously silent about what LNP technology is used in its vaccine, if not what is described by its own co-authors in the Moderna/NIH preprint. Moderna has not requested retraction of the Moderna/NIH preprint or otherwise submitted a correction of it. Instead, when it came time to publish the official version of that preprint in the scientific publication *Nature*, it simply excised the relevant details about the LNP technology it was using.

48. Nonetheless, another preclinical study of Moderna's COVID-19 vaccine, authored by Corbett et al. and published on the website of *The New England Journal of Medicine* on July 28, 2020, confirmed that the mRNA was encapsulated in an LNP "as described previously" and cited a prior Moderna publication that discloses the same lipid molar ratio as the Moderna/NIH preprint.[13] Four of the article's authors were affiliated with Moderna at the time of the article's publication. Moderna has not requested retraction of the Corbett 2020 *The New England Journal*

[13] *See* Corbett et al., "Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates," *NEJM* 383;16:1544-1555, 1546 (2020) (citing Hassett et al., "Optimization of Lipid Nanoparticles for Intramuscular Administration of mRNA Vaccines," *Mol. Ther. Nucl. Acids* 15:1-11, 8 (2019)), *available at* https://www.nejm.org/doi/full/10.1056/nejmoa2024671#.

of Medicine article or otherwise submitted a correction of the Corbett 2020 *The New England Journal of Medicine* article.

49. What is more, on May 14, 2021, Moderna submitted an international patent application titled "Coronavirus RNA Vaccines and Methods of Use," which published on August 12, 2021, as International Patent Publication WO 2021/159130. In that application, "Example 1:Phase 1 Clinical Trial" identifies the specific ionizable lipid used in the Phase I clinical trial of Moderna's vaccine as "heptadecan-9-yl 8 ((2 hydroxyethyl)(6 oxo 6-(undecyloxy)hexyl) amino)octanoate 20," also known as SM-102, which in its ionized state is positively charged (cationic).[14] Example 1 also recites that the particles used in the Phase I clinical trial of Moderna's vaccine are prepared with the same lipid molar ratio identified in the Moderna/NIH preprint, i.e.: 50 mol % of an ionizable lipid that is cationic; 10 mol % of a phospholipid (DSPC); 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles (PEG-lipid).[15]

50. Notwithstanding its repeated statements in published articles and its patent application, Moderna publicly denied infringement of Arbutus's patents, ostensibly on the basis that the LNPs in Moderna's COVID-19 vaccine manufactured and sold initially on the basis of EUA and now with full FDA approval differed from the LNPs in its Phase I clinical trial. But while Moderna was denying infringement in public statements, its Senior Vice President and

[14] *See* International Patent Publication WO 2021/159130 at 49.
[15] *See id.* ("The SARS-CoV-2 mRNA vaccine. . . was a lipid nanoparticle (LNP) dispersion of an mRNA encoding the prefusion stabilized spike protein SARS-CoV-2 formulated in LNPs composed of four (4) lipids (50 mol% ionizable lipid heptadecan-9-yl 8 ((2 hydroxyethyl)(6 oxo 6-(undecyloxy)hexyl)amino)octanoate 20 (Compound 1); 10 mol% 1,2 distearoyl sn glycero-3 phosphocholine (DSPC); 38.5 mol% cholesterol; and 1.5 mol% l-monomethoxypolyethyleneglycol-2,3-dimyristylglycerol with polyethylene glycol of average molecular weight 2000 (PEG2000 DMG)).").

Deputy General Counsel, Shaun Ryan, submitted on February 23, 2021, a sworn statement under penalty of perjury in support of one of its IPR appeals to the United States Court of Appeals for the Federal Circuit. In that sworn declaration, he stated that the "lipid carrier particle" used in its Phase I study—described in the Moderna/NIH preprint and WO 2021/159130 as being within the scope at least of Claim 1 of the '069 Patent—is the same as the one that was "ultimately approved" for use in its product.[16]

51. Distribution of the Accused Product and its administration to persons in the United States and around the world commenced immediately after the FDA granted Moderna's COVID-19 vaccine an EUA on December 18, 2020. In 2021, Moderna shipped 807 million doses.[17] As of February 24, 2022, Moderna had signed advanced purchase agreements worth approximately $19 billion for all of 2022.[18] As of May 6, 2021, Moderna had signed advance purchase agreements covering more than one billion doses.[19] And from December 18, 2020, through February 24, 2022, more than 200 million doses of Moderna's COVID-19 vaccine had been administered to people throughout the United States.[20] Moderna's vaccine doses made in the United States and administered in the United States were distributed to hospitals, pharmacies,

[16] Declaration of Shaun Ryan, Mot. to Supplement the Record to Provide Evidence of Standing, Dkt. No. 18, 11-12 ¶¶ 3-4, *Moderna TX, Inc. v. Arbutus Biopharma Corp.*, No. 2020-2329 (Fed. Cir.).

[17] Press Release, Moderna, Moderna Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Provides Business Updates (Feb. 24, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates/default.aspx.

[18] *Id.*

[19] Press Release, Moderna, Moderna Reports First Quarter Fiscal Year 2021 Financial Results and Provides Business Updates (May 6, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-reports-first-quarter-fiscal-year-2021-financial-results.

[20] COVID-19 Vaccinations in the United States, CDC (last visited Feb. 25, 2022), https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

clinics, and numerous other entities for the benefit of individual vaccine recipients in the United States. All of the manufacturing and sales of vaccines distributed in the United States were for the benefit of the American public. Millions more doses, including doses made in the United States, have been administered abroad.

52. On June 1, 2021, Moderna announced that it had initiated the FDA process for a BLA—i.e., for the full-fledged licensure of its COVID-19 vaccine. As of February 24, 2022, Moderna's COVID-19 vaccine had received at least emergency authorization from more than 70 countries,[21] including Canada, Israel, the United Kingdom, Switzerland, Singapore, Qatar, Taiwan, and the Philippines, as well as from the European Union.[22] On January 31, 2022, the FDA approved Moderna's BLA for its COVID-19 vaccine.[23]

53. In May 2021, Moderna announced that it had begun exporting from the United States doses of its COVID-19 vaccine that were manufactured in facilities in the United States.[24] Those doses were made in the United States and sold to foreign governments or other foreign entities for the benefit of individuals outside the United States.

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[21] Press Release, Moderna, Moderna Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Provides Business Updates (Feb. 24, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates/default.aspx.

[22] *See id.*

[23] Press Release, Moderna, Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine Spikevax (Jan. 31, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax/default.aspx.

[24] Moderna Reply Br. at 22, Dkt. No. 41, *Moderna TX, Inc. v. Arbutus Biopharma Corp.* (Fed. Cir. No. 2020-2329) (citing Vaccine Exports From U.S. Accelerate as Moderna Ships Abroad, Bloomberg.com (May 20, 2021), https://www.bloomberg.com/news/articles/2021-05-20/moderna-starts-shipping-vaccine-from-u-s-boosting-shot-exports).

54. Moderna also has contracted with a number of companies around the world to manufacture its COVID-19 vaccine.[25] This includes several companies that employ facilities in the United States to manufacture Moderna's vaccine.[26]

55. Moderna chose to contract with companies to establish sites outside the United States that would combine the components of its COVID-19 vaccine, which it described as "independent US and international supply chains."[27]

56. However, these sites outside the United States still relied on manufacturing in the United States by Moderna or at Moderna's direction to supply them components of the Accused Product. Moderna manufactured the components of its infringing product—mRNA [redacted]—in the United States and then supplied them, or cause them to be supplied, outside of the United States to be combined to make the finished COVID-19 vaccine.[28] These components constitute a substantial portion of Moderna's COVID-19 vaccine and were combined outside the United States at Moderna's direction.

57. Moderna's COVID-19 vaccine is [redacted][29]:

[25] *See*, *e.g.*, Press Release, Moderna, Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna's Vaccine (mRNA-1273) Against Novel Coronavirus (May 1, 2020), https://investors.modernatx.com/news-releases/news-release-details/moderna-and-lonza-announce-worldwide-strategic-collaboration.
[26] *Id.*; *see also, e.g.*, Press Release, Moderna, Baxter BioPharma Solutions and Moderna Announce Agreement for Fill/Finish Manufacturing of the Moderna COVID-19 Vaccine in the U.S. (Mar. 8, 2021), https://investors.modernatx.com/news-releases/news-release-details/baxter-biopharma-solutions-and-moderna-announce-agreement.
[27] MRNA-GEN-00854857.
[28] MRNA-GEN-01424228.
[29] MRNA-GEN-00031755 at -761.

58. These components are especially made or adapted for Moderna's COVID-19 vaccine. The mRNA component encodes a modified version of the SARS-CoV-2 spike (S) protein, which is specifically designed for use in the COVID-19 vaccine.

Neither component is a staple item and neither is used in any commercial product other than Moderna's COVID-19 vaccine.

F. Arbutus and Genevant Attempt to Negotiate a License with Moderna

59. Plaintiffs tried to avoid the need to file this lawsuit.

60. Many companies have paid Plaintiffs for a license to use the breakthrough LNP technology at issue here, including several companies developing COVID-19 vaccines and several other companies with which Genevant has ongoing development collaborations. The research and development facilitated by these and other licenses has resulted in product candidates across a variety of conditions.

61. Plaintiffs would have preferred to resolve their dispute with Moderna with a mutually acceptable license from Genevant. And Plaintiffs have long sought to do just that. In proposing such a license, Plaintiffs did not wish to minimize the importance of Moderna's extensive efforts to manufacture and distribute billions of doses of its COVID-19 vaccine in the

midst of a global pandemic. Those efforts have been vitally important and have saved countless lives. Rather, Plaintiffs sought only the fair and reasonable compensation to which they are entitled by law for their contributions to Moderna's COVID-19 vaccine—contributions that were the product of decades of pioneering work by Arbutus scientists, many now at Genevant companies, including during periods when it was uncertain whether mRNA vaccines could ultimately be made to work.

62. Unfortunately, Moderna has consistently declined to engage meaningfully in licensing discussion, necessitating this lawsuit.

63. On November 23, 2020, Arbutus and Genevant sent Moderna a letter stating that the Accused Product may infringe claims of each of the then-issued Asserted Patents and offering to discuss the terms of a collaboration or license to further both parties' goal of ending the COVID-19 pandemic. Moderna acknowledged receipt of this letter on November 25, 2020.

64. On December 10, 2020, Moderna sent a letter to Arbutus and Genevant stating that Moderna was "open to hearing [Genevant's] proposal for a partnership or patent license."

65. Upon receiving the Arbutus and Genevant proposal, however, Moderna declined to negotiate. Moderna also declined repeated requests to provide samples or non-public documents, even under a confidentiality agreement, to support any assertion that it does not infringe the Asserted Patents, including those in which it invested substantial resources and time to challenge, throughout 2020 and 2021, before the United States Patent and Trademark Office and the United States Court of Appeals for the Federal Circuit.

G. Moderna Refuses to Compensate Arbutus and Genevant for Using Their Technology

66. Despite Arbutus and Genevant's repeated efforts, Moderna has refused to take a license from, partner with, or otherwise compensate Plaintiffs for their contribution to Moderna's

COVID-19 vaccine. Instead, Moderna continues to infringe the Asserted Patents directly and indirectly, without authority and with actual knowledge of, or reckless disregard for, the fact that its actions constitute infringement of the Asserted Patents.

67. Arbutus and Genevant fully support Moderna's efforts to supply vaccines to people in the United States and worldwide and in no way seek to interfere with those efforts. Accordingly, no injunctive relief is sought in this case.

68. However, Moderna has made extensive use of, and earned billions in profits exploiting, Arbutus's patented technology, including the technology described and claimed in the Asserted Patents. Moderna's actions have caused harm, and continue to cause harm, to Arbutus and Genevant. Arbutus and Genevant have no choice but to defend their proprietary and patented technology and seek fair and reasonable compensation for the value of their innovation.[30]

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 8,058,069

69. Paragraphs 1 through 64 are incorporated by reference as if fully set forth herein.

70. The United States Patent and Trademark Office duly and legally issued the '069 Patent to one of Arbutus's predecessor companies on November 15, 2011. The '069 Patent is titled "Novel Lipid Formulations for Nucleic Acid Delivery."

71. Arbutus owns, and at all relevant times has owned, the '069 Patent.

[30] The allegations herein are exemplary and without prejudice to Arbutus and Genevant's infringement contentions. In providing these allegations, Arbutus and Genevant do not convey or imply any particular claim constructions or the precise scope of the claims. Arbutus and Genevant's claim construction contentions regarding the meaning and scope of the claim terms will be provided under the Court's scheduling order and this District's Local Rules.

72. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the ’069 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

73. Claims of the ’069 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

74. Moderna has directly infringed and continues to directly infringe claims of the ’069 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product incorporating Arbutus’s patented LNP delivery technology covered by the ’069 Patent, without authority or license to do so, during the term of the ’069 Patent.

75. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the ’069 Patent under 35 U.S.C. § 271(b) by encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the ’069 Patent.

76. Moderna has contributed, and continues to contribute, to the infringement of one or more claims of the ’069 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the ’069 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the ’069 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

77. Moderna has also infringed and continues to infringe the ’069 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United

States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '069 patent if such combination occurred within the United States.

78. Moderna has also infringed and continues to infringe the '069 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '069 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

79. For example, Claim 1 of the '069 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 4 mol % to 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

80. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Asserted Product is an mRNA which encodes the COVID-19 spike protein.

81. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: an ionizable cationic lipid (SM-102); a phospholipid (DSPC); cholesterol; and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid conjugate).

82. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles comprising the following lipids in the following ratio of the total lipid present in the particle: 50 mol % of an ionizable cationic lipid; 10 mol % of a phospholipid; 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

83. Moderna has known of the '069 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since then. Moderna has long been aware of, and has actively monitored Arbutus's patent estate, including the '069 Patent.[31] Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to invalidate three of Arbutus's LNP-related patents, including the '069 Patent, through *inter partes* review; and Moderna has repeatedly made public representations regarding Arbutus's LNP technology and patents.[32] Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a

[31] *See, e.g.*, Moderna Mot. at 4-5, Dkt. No. 18, *Moderna TX, Inc. v. Arbutus Biopharma Corp*. (Fed. Cir. No. 2020-2329).
[32] *See, e.g.*, Moderna Mot. at 5, Dkt. No. 18, *Moderna TX, Inc. v. Arbutus Biopharma Corp*. (Fed. Cir. No. 2020-2329); Press Release, Moderna, Statement from Moderna on Patent Trial and Appeal Board (PTAB) Ruling (July 24, 2020), https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-patent-trial-and-appeal-board-ptab-ruling.

substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

84. Moderna actively and knowingly has infringed the '069 Patent and actively and knowingly has induced infringement of the '069 Patent by others. After Moderna knew or should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA[33] to market and sell its vaccine in the United States with the specific intent to induce customers to purchase the Accused Product. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad,[34] and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '069 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna markets the Accused Product to governments and other entities with the intent for healthcare professionals to administer the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

[33] Press Release, Moderna, Moderna Announces Initiation of Rolling Submission of Biologics License Application (BLA) with U.S. FDA for the Moderna COVID-19 Vaccine (June 1, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-initiation-rolling-submission-biologics; Press Release, Moderna, Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine Spikevax (Jan. 31, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax/default.aspx.

[34] Press Release, Moderna, Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna's Vaccine (mRNA-1273) Against Novel Coronavirus (May 1, 2020), https://investors.modernatx.com/news-releases/news-release-details/moderna-and-lonza-announce-worldwide-strategic-collaboration.

85. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '069 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '069 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '069 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '069 Patent by administering the Accused Product in the United States.

86. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '069 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying or causing to be supplied from the United States a component or all or a substantial portion of components of the Accused Product.

87. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

88. Moderna has undertaken its infringing actions despite knowing that such actions infringe one or more claims of the '069 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '069 Patent.

89. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '069 Patent.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 8,492,359

90. Paragraphs 1 through 83 are incorporated by reference as if fully set forth herein.

91. The United States Patent and Trademark Office duly and legally issued the '359 Patent to one of Arbutus's predecessor companies on July 23, 2013. The '359 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

92. Arbutus owns, and at all relevant times has owned, the '359 Patent.

93. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '359 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

94. Claims of the '359 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

95. Moderna has directly infringed and continues to directly infringe claims of the '359 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product incorporating Arbutus's patented LNP delivery technology covered by the '359 Patent, without authority or license to do so, during the term of the '359 Patent.

96. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the '359 Patent under 35 U.S.C. § 271(b) by

actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the '359 Patent.

97. Moderna has contributed, and continues to contribute to the infringement of one or more claims of the '359 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the '359 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '359 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

98. Moderna has also infringed and continues to infringe the '359 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '359 patent if such combination occurred within the United States.

99. Moderna has also infringed and continues to infringe the '359 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '359 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

100. For example, Claim 1 of the '359 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

101. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

102. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: an ionizable cationic lipid (SM-102); a phospholipid (DSPC); cholesterol; and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid conjugate).

103. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles comprising the following lipids in the following ratio of the total lipid present in the particle: 50 mol % of an ionizable cationic lipid; 10 mol % of a phospholipid; 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

104. Moderna has known of the '359 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since then. Moderna has long been aware of and actively monitored Arbutus's patent estate. Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to

invalidate three of Arbutus's LNP-related patents through *inter partes* review; and Moderna has repeatedly made public statements regarding Arbutus's LNP technology and patents. The '359 Patent is in the same family as, and is cited on the face of, the '435 Patent that Moderna challenged in *inter partes* review. Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

105. Moderna actively and knowingly has infringed the '359 Patent and actively and knowingly has induced infringement of the '359 Patent by others. After Moderna knew or should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '359 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce customers to purchase the Accused Product. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad, with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna actively markets the Accused Product to governments and other entities with the intent for healthcare professionals to administer the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

106. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '359 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '359 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '359 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '359 Patent by administering the Accused Product in the United States.

107. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '359 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying a component or all or a substantial portion of components of the Accused Product.

108. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

109. Moderna has undertaken its infringing actions despite knowing that such actions infringe one or more claims of the '359 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '359 Patent.

110. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '359 Patent.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 8,822,668

111. Paragraphs 1 through 102 are incorporated by reference as if fully set forth herein.

112. The United States Patent and Trademark Office duly and legally issued the '668 Patent to one of Arbutus's predecessor companies on September 2, 2014. The '668 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

113. Arbutus owns, and at all relevant times has owned, the '668 Patent.

114. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '668 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

115. Claims of the '668 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof and methods of using them.

116. Moderna has directly infringed and continues to directly infringe claims of the '668 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product incorporating Arbutus's patented LNP delivery technology covered by the '668 Patent, without authority or license to do so, during the term of the '668 Patent.

117. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the '668 Patent under 35 U.S.C. § 271(b) by

actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the '668 Patent.

118. Moderna has contributed, and continues to contribute, to the infringement of one or more claims of the '668 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the '668 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '668 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

119. Moderna has also infringed and continues to infringe the '668 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '668 patent if such combination occurred within the United States.

120. Moderna has also infringed and continues to infringe the '668 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '668 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

121. For example, Claim 1 of the '668 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising up to 49.5 mol % of the total lipid present in the particle and comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

122. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

123. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: an ionizable cationic lipid (SM-102); a non-cationic lipid comprising a mixture of a phospholipid and cholesterol; and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid conjugate).

124. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles comprising the following lipids in the following ratio of the total lipid present in the particle: 50 mol % of an ionizable cationic lipid; 10 mol % of a phospholipid; 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

125. When used as intended, the Accused Product infringes the '668 Patent's method claims.

126. For example, Claim 20 of the '668 patent recites "[a] method for treating a disease or disorder in a mammalian subject in need thereof, the method comprising:

administering to the mammalian subject a therapeutically effective amount of a nucleic acid-lipid particle of claim 1."

127. Moderna's COVID-19 vaccine is intended for use in a method for treating a disease or disorder in a mammalian subject in need thereof, namely vaccination of a human against COVID-19. Moderna's COVID-19 vaccine comprises the nucleic acid-lipid particles of Claim 1 and it is intended for administration to a human in need thereof. Moderna's COVID-19 vaccine comprises a therapeutically effective amount of a nucleic acid-lipid particle of Claim 1. When used as intended, and as Moderna specifically instructs and encourages that it be used, the Accused Product infringes Claim 20.

128. Moderna has known of the '668 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since then. Moderna has long been aware of and actively monitored Arbutus's patent estate. Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to invalidate three of Arbutus's LNP-related patents through *inter partes* review; and Moderna has repeatedly made public statements regarding Arbutus's LNP technology and patents. The '668 Patent is in the same family as, and is cited on the face of, the '435 Patent that Moderna challenged in *inter partes* review. Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

129. Moderna actively and knowingly has infringed the '668 Patent and actively and knowingly has induced infringement of the '668 Patent by others. After Moderna knew or

should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States, with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '668 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna actively markets the Accused Product to governments and other entities with the intent for healthcare professionals to infringe by administering the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

130. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '668 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '668 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times

after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '668 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '668 Patent by administering the Accused Product in the United States.

131. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '668 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying a component or all or a substantial portion of components of the Accused Product.

132. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

133. Moderna has undertaken its infringing actions despite knowing that such actions infringe one or more claims of the '668 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '668 Patent.

134. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '668 Patent.

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 9,364,435

135. Paragraphs 1 through 124 are incorporated by reference as if fully set forth herein.

136. The United States Patent and Trademark Office duly and legally issued the '435 Patent to one of Arbutus's predecessor companies on June 14, 2016. The '435 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

137. Arbutus owns, and at all relevant times has owned, the '435 Patent.

138. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the ’435 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

139. Claims of the ’435 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof and methods of using them.

140. Moderna has directly infringed and continues to directly infringe claims of the ’435 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product incorporating Arbutus’s patented LNP delivery technology covered by the ’435 Patent, without authority or license to do so, during the term of the ’435 Patent.

141. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the ’435 Patent under 35 U.S.C. § 271(b) by actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the ’435 Patent.

142. Moderna has contributed, and continues to contribute, to the infringement of one or more claims of the ’435 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the ’435 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the ’435 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

143. Moderna has also infringed and continues to infringe the ’435 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United

States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '435 patent if such combination occurred within the United States.

144. Moderna has also infringed and continues to infringe the '435 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '435 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

145. The Accused Product infringes at least Claim 7 of the '435 Patent.

146. Claim 7 of the '435 Patent depends from Claims 1 and 5. Claim 1 of the '435 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid present in the particle; (c) non-cationic lipid comprising from 13 mol % to 49.5 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle." Claim 5 further requires "[t]he nucleic acid-lipid particle of claim 1, wherein the non-cationic lipid comprises a mixture of a phospholipid and cholesterol or a derivative thereof." Claim 7 further requires "[t]he nucleic acid-lipid particle of claim 5, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle."

147. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

148. The Accused Product comprises an ionizable cationic lipid (SM-102), a non-cationic lipid (a mixture of phospholipid and cholesterol), and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid conjugate).

149. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles comprising the following lipids in the following ratio of the total lipid present in the particle: 50 mol % of an ionizable cationic lipid; 48.5 mol % of a non-cationic lipid; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

150. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles where the non-cationic lipid comprises a mixture of a phospholipid and cholesterol. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles where 10 mol % of the total lipid present in the particle is a phospholipid.

151. When used as intended, the Accused Product infringes the ’435 Patent’s method claims.

152. For example, Claim 17 of the ’435 Patent recites a “method for treating a disease or disorder in a mammalian subject in need thereof, the method comprising: administering to the mammalian subject a therapeutically effective amount of a nucleic acid-lipid particle of claim 1.”

153. The Accused Product is intended for use in a method for treating a disease or disorder in a mammalian subject in need thereof, namely vaccination of a human against COVID-19. The Accused Product comprises the nucleic acid-lipid particles of Claim 1 and it is intended for administration to a human in need thereof. The Accused Product comprises a therapeutically effective amount of a nucleic acid-lipid particle of Claim 1. When used as intended, and as Moderna specifically instructs and encourages that it be used, the Accused Product infringes Claim 17.

154. Moderna has known of the '435 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since then. Moderna has long been aware of and actively monitored Arbutus's patent estate. Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to invalidate three of Arbutus's LNP-related patents, including the '435 Patent, through *inter partes* review, and Moderna has repeatedly made public statements regarding Arbutus's LNP technology and patents. Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

155. Modern actively and knowingly has infringed the '435 Patent and actively and knowingly induced infringement of the '435 Patent by others. After Moderna knew or should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the

Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '435 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna actively markets the Accused Product to governments and other entities with the intent for healthcare professionals to infringe by administering the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

156. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '435 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '435 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '435 Patent, it contracted with others to manufacture the Accused Product,

both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '435 Patent by administering the Accused Product in the United States.

157. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '435 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying a component or all or a substantial portion of components of the Accused Product.

158. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

159. Moderna has undertaken its infringing actions despite knowing that such actions infringed one or more claims of the '435 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '435 Patent.

160. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '435 Patent.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 9,504,651

161. Paragraphs 1 through 148 are incorporated by reference as if fully set forth herein.

162. The United States Patent and Trademark Office duly and legally issued the '651 Patent to one of Arbutus's predecessor companies on November 29, 2016. The '651 Patent is titled "Lipid Compositions for Nucleic Acid Delivery."

163. Arbutus owns, and at all relevant times has owned, the '651 Patent.

164. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '651 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

165. Claims of the ’651 Patent cover, among other things, lipid vesicle formulations comprising mRNA.

166. Moderna has directly infringed and continues to directly infringe the claims of the ’651 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product, incorporating Arbutus’s patented LNP delivery technology covered by the ’651 Patent, without authority or license to do so, during the term of the ’651 Patent.

167. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the ’651 Patent under 35 U.S.C. § 271(b) by actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the ’651 Patent.

168. Moderna has contributed, and continues to contribute, to the infringement of one or more claims of the ’651 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the ’651 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the ’651 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

169. Moderna has also infringed and continues to infringe the ’651 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a

manner that would infringe the '651 patent if such combination occurred within the United States.

170. Moderna has also infringed and continues to infringe the '069 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '651 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

171. For example, Claim 1 of the '651 Patent recites a "lipid vesicle formulation comprising: (a) a plurality of lipid vesicles, wherein each lipid vesicle comprises: a cationic lipid; an amphipathic lipid; and a polyethyleneglycol (PEG)-lipid; and (b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles." Claim 9 of the '651 Patent further requires "[t]he lipid vesicle formulation of claim 1, wherein each lipid vesicle is a lipid-nucleic acid particle."

172. The Accused Product is a lipid vesicle formulation comprising mRNA and lipid vesicles. The mRNA in the Accused Product encodes the COVID-19 spike protein.

173. The Accused Product comprises a lipid vesicle comprising the following lipids: an ionizable cationic lipid (SM-102); an amphipathic lipid (DSPC); and a PEG-lipid.

174. Upon information and belief, in connection with the Accused Product, Moderna makes a lipid vesicle formulation wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles.

175. On information and belief, Moderna has known of the '651 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since

then. Moderna has long been aware of and actively monitored Arbutus's patent estate. Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to invalidate three of Arbutus's LNP-related patents through *inter partes* review, and Moderna has repeatedly made public statements regarding Arbutus's LNP technology and patents. Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

176. Moderna actively and knowingly has infringed the '651 Patent and actively and knowingly induced infringement of the '651 Patent by others. After Moderna knew or should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '651 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad, with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna actively markets the Accused Product to governments and other

entities with the intent for healthcare professionals to administer the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

177. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '651 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '651 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '651 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '651 Patent by administering the Accused Product in the United States.

178. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '651 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of Moderna's COVID-19 vaccine into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying a component or all or a substantial portion of components of the Accused Product.

179. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

180. Moderna has undertaken their infringing actions despite knowing that such actions infringed one or more claims of the '651 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '651 Patent.

181. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '651 Patent.

COUNT 6: INFRINGEMENT OF U.S. PATENT NO. 11,141,378

182. Paragraphs 1 through 167 are incorporated by reference as if fully set forth herein.

183. The United States Patent and Trademark Office duly and legally issued the '378 Patent to Arbutus on October 12, 2021. The '378 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

184. Arbutus owns, and at all relevant times has owned, the '378 Patent.

185. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '378 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

186. Claims of the '378 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

187. Moderna has directly infringed and continues to directly infringe claims of the '378 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product incorporating Arbutus's patented LNP delivery technology covered by the '378 Patent, without authority or license to do so, during the term of the '378 Patent.

188. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the '378 Patent under 35 U.S.C. § 271(b) by

actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the '378 Patent.

189. Moderna has and continues to contribute to the infringement of one or more claims of the '378 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the '378 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '378 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

190. Moderna has also infringed and continues to infringe the '378 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '378 patent if such combination occurred within the United States.

191. Moderna has also infringed and continues to infringe the '378 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '378 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

192. For example, Claim 1 of the '378 Patent recites a "nucleic acid-lipid particle consisting essentially of: (a) an RNA; (b) a cationic lipid having a protonatable tertiary amine; (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the phospholipid consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle." An ionizable lipid having a protonatable tertiary amine becomes a cationic lipid.

193. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

194. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: an ionizable cationic lipid (SM-102); a non-cationic lipid comprising a mixture of a phospholipid and cholesterol; and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid).

195. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises a cationic lipid having a protonatable tertiary amine; 10 mol % of a phospholipid; 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

196. The '378 Patent issued on October 12, 2021. That day, Genevant sent Moderna an email notice that Moderna may be infringing one or more claims of the '378 Patent.

197. Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the

United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

198. Moderna actively and knowingly has infringed the '378 Patent and actively and knowingly induced infringement of the '378 Patent by others. After Moderna knew or should have known that the Accused Product infringed, Moderna continued to seek and has now received full FDA approval for its Accused Product, with the specific intent to induce customers to purchase them and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product infringed, it has maintained active contracts with multiple companies to manufacture the Accused Product, both in the United States and abroad, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '378 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna is continuing to seek and negotiate similar contracts with companies to manufacture the Accused Product. Upon information and belief, Moderna actively markets the Accused Product to governments and other entities with the intent for healthcare professionals to infringe by administering the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

199. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '378 Patent, knowing the same to be especially made or

especially adapted for use in the infringement of the '378 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it continued to pursue and has now obtained full FDA approval to market and sell the Accused Product in the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '378 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '378 Patent by administering the Accused Product in the United States.

200. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '378 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying a component or all or a substantial portion of components of the Accused Product.

201. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

202. Moderna has undertaken its infringing actions despite knowing that such actions infringe one or more claims of the '378 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '378 Patent.

203. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '378 Patent.

PRAYER FOR RELIEF

WHEREFORE, Arbutus and Genevant respectfully request that this Court enter judgment in their favor against Moderna and grant the following relief:

A. A judgment that Moderna has infringed or will infringe each of the Asserted Patents under 35 U.S.C. § 271(a), (b), (c) or (f) by making, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product, or actively inducing someone to do the same or contributing to the same, or supplying or causing to be supplied from the United States a component or all or a substantial portion of components of the Accused Product, during the term of each of the Asserted Patents;

B. An award of damages sufficient to compensate Arbutus and Genevant for Moderna's infringement under 35 U.S.C. § 284, in no event less than a reasonable royalty on all infringing sales or other dispositions of Accused Product;

C. A judgment that the infringement has been willful and an enhancement of damages;

D. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

E. An award of Arbutus's and Genevant's costs and expenses in this action;

F. An award of pre- and post-judgement interest; and

G. Such other and further relief as this court may deem just and proper, except that Arbutus and Genevant DO NOT seek any form of injunctive relief concerning the Accused Product.

JURY DEMAND

Arbutus and Genevant, by and through undersigned counsel, hereby demand, pursuant to Fed. R. Civ. P. 38, a trial by jury on all claims so triable in this action.

Dated: May 1, 2024

/s/ Nathan R. Hoeschen

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